

ATTACHMENT A
Remarks

Claims 24-66 are pending in the present application. By this Amendment, in conjunction with the contemporaneously filed RCE, Applicant has amended claims 24, 28, 29, 43, 50 and 51; and added new claims 64-66. Applicant respectfully submits that the present application is in condition for allowance based on the discussion which follows.

As an initial point, Applicant greatly appreciates the Examiner conducting an Examiner Interview with his representative, Mr. Stephen Weyer, on June 27, 2007. By this Amendment, Applicant has amended the claims as discussed during that interview. Specifically, by this Amendment, Applicant has more clearly recited that the method is directed to a glycoalkaloid preparation which includes removing free sugar from a solid glycoalkaloid preparation. As agreed during the Examiner Interview, the cited prior art of Guerrero (U.S. Patent No. 3,960,839) (hereinafter "Guerrero") is specifically directed to glycoalkaloid solutions, not solid preparations. In addition, by this Amendment, Applicant has added new claims 64-66, which recite removing essentially all free sugar from a glycoalkaloid preparation (claim 64), a resulting preparation (claim 65) and a medicinal composition (claim 66) based on prior claims 24, 33 and 34, presented in the June 25, 2004 Amendment. Therefore, new claims 64-66 do not present new matter.

Turning to the subject of the final Office Action, claims 24-29, 33-39, 43-50 and 54-60 were rejected under 35 U.S.C. § 102(b) as being anticipated by Guerrero. Further, claims 24-63 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Guerrero in combination with Cham et al. (Cancer Letters, 55 (1990) 221-225) (hereinafter "Cancer Letters").

The present method, as currently amended, is distinguishable over Guerrero, which fails to teach or in any way make obvious a glycoalkaloid preparation method in which free sugar is removed from a solid glycoalkaloid preparation. To the contrary, Guerrero is specifically directed to a series of process steps starting with a glycoalkaloid solution which undergoes several steps, eventually hydrolyzing the glycoalkaloid, in solution, to remove the glycoside from the solasodine. However, at not point is free sugar removed from a solid glycoalkaloid preparation.

Turning to the specific steps of Guerrero in more detail, the starting material is a glycoalkaloid solution in the form of an aqueous alcoholic extract (Guerrero, column 3, lines 26-28). Next, the glycoalkaloid solution's pH is raised (alkalization) and glycosides of solasodine may be recovered by filtration or centrifugation (Guerrero, column 3, lines 33-35). Then, the glycosides of solasodine are hydrolyzed in a solution comprising the glycosides, isopropanol, HCl and water; and the resulting solasodine is recovered (Guerrero, column 3, lines 36-38). Finally, the solasodine precipitate is washed, essentially leaving pure solasodine (Guerrero, column 3, lines 45-49).

The present process is distinguishable from Guerrero in that the present method includes removing soluble free sugar from a solid glycoalkaloid preparation.

Conversely, Guerrero fails to teach any process for removing free sugar from a solid glycoalkaloid preparation. Arguably, the only process of Guerrero which may remove free sugar, is during the alkalization of the glycoalkaloid solution, but, during alkalization of the glycoalkaloid solution, free sugar is not removed from a solid glycoalkaloid preparation. Further, although the final step of Guerrero is a washing step of solid solasodine, since solasodine lacks the glycoside, the final step of Guerrero fails to

anticipate the present method of removing free sugar from a solid glycoalkaloid preparation. Accordingly, the present method is novel and non-obvious in view of Guerrero.

In addition, Applicant respectfully submits that the dependent claims are not anticipated or obvious in view of the prior art. For example, claim 29 recites that essentially all the free sugars are removed from the glycoalkaloid preparation by washing with an aqueous solvent. The prior art fails to teach or make obvious removing essentially all free sugar, let alone all free sugar, by washing a solid glycoalkaloid preparation with an aqueous solvent, as claimed.

Further, Applicant respectfully submits that claims 33-41 are novel and non-obvious in view of the prior art. For example, claim 33 recites a glycoalkaloid preparation produced according to the method of claim 24. As described in the specification as filed, the present method produces a glycoalkaloid preparation which includes a step of removing free sugar from the solid preparation. The resulting product of the claimed process is a preparation having free sugar removed, and thus a glycoalkaloid preparation which is purer in terms of free sugar content than prior glycoalkaloid preparations which do not have free sugar removed. As a result, the presently claimed product is distinguishable over prior glycoalkaloid preparations in terms of purity resulting from free sugar being removed. Thus, the present glycoalkaloid is a novel and non-obvious preparation over prior art glycoalkaloid preparations.

In addition, evidence of enhanced efficacy of the present glycoalkaloid preparation, produced in accordance with the present method, is demonstrated in the specification as filed. Therefore, the enhanced efficacy of the present product

demonstrated that the product produced by the method as recited in claims 33-41 is novel and non-obvious over prior glycoalkaloid preparations.

Finally, as discussed above, by this Amendment, Applicant has added new claims 64-66, directed to one specific form of the present invention in which essentially all free sugar is removed from the glycoalkaloid preparation. Claims 64-66 are further distinguishable over the prior art, which fails to teach or in any way make obvious removing essentially all free sugar from a glycoalkaloid preparation (claim 64) or the resulting essentially without free sugar preparation and medicinal composition (claims 65 and 66).

In view of the foregoing, Applicant respectfully submits that the present application is in condition for allowance.

END REMARKS